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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER THAKUR, VIREN A	
			ART UNIT	PAPER NUMBER
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			07/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/581,200	Applicant(s) TAKASHIMA ET AL.	
	Examiner VIREN THAKUR	Art Unit 1782	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14, 16-23 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 14, 16-19, 22, 23 and 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/20/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. Regarding the information disclosure statement filed January 20, 2010, it is noted that it is not clear as to which document corresponds to which of the cited foreign patent documents. One of the documents filed January 20, 2010 appears to be an examination report and the other is an English specification. Regarding the English specification, it is not clear as to which of the listed Taiwanese documents has been submitted.

Terminal Disclaimer

2. The terminal disclaimer filed on April 22, 2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent issuing from application Serial No. 11/511,321, 10/532,727, 11/434,069 and 12/297,452 has been reviewed and is accepted. The terminal disclaimer has been recorded. The double patenting rejections have thus been withdrawn.

Response to Amendment

3. As a result of the amendment to the claims and the perfecting of foreign priority, those rejections relying on Takahashi et al. (JP 2004-222719) have been withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation, “the green tea extract used as a raw material is a tea extract extracted from leaves of the genus *Camellia* which have been treated to contact with carbon dioxide in a supercritical state.” This limitation is not clear as to whether the tea extract extracted from the tea leaves has been treated with supercritical carbon dioxide, or whether the leaves of the genus *Camellia* have been treated with supercritical carbon dioxide.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 12,16,17, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Funahashi et al. (JP 2000-166466) in view of Hall, Jr. et al. (US 4229612), Katz (US 4324840), Klima et al. (US 4976979) and in further view of Bailey et al. (US 6210679) for the reasons given in the previous Office Action, mailed November 30, 2009.

Claim 17 was previously objected to and thus withdrawn from consideration. As a result of the amendment to the claims, claim 17 has now been considered. Claim 17 recites that the organic solvent is ethanol. Regarding this limitation, Funahashi et al. teaches using ethanol as the organic solvent (see paragraph 0003 of the machine translation, for instance). This has been further evidenced by Bailey et al. (column 3, lines 47-56 and column 5, lines 62-64).

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 12,16,17 and 22, above, and in further view of Tsai et al. (US 4935256), for the reasons given in the previous Office Action, mailed November 30, 2009.

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 12, 16, 17 and 22, above, and in further view of Clausi et al. (EP0167399), Wolnzach (DE3414767) and Wang (CN1141727).

Regarding claim 18, it is noted that the claim is not clear as to whether it is the "raw material" or the leaves from the genus *Camellia* that have been contacted with

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supercritical carbon dioxide. Regarding the former, it is noted that the use of supercritical carbon dioxide as well as adsorbents has been well recognized in the art, for the purpose of decaffeinating products, as evidenced by Klima (see example 1 and column 3, lines 18-23 and lines 24-31). Regarding the latter, the combination as applied to claims 12, 14, 16, 17 and 22 appear silent in this regard. Additionally, however, Clausi et al. teaches a green tea leaf that has been treated with supercritical carbon dioxide (see example 1 and example 2). Although Clausi et al. discloses fermenting the green tea leaves (to thus produce a black tea flavor), if one did not desire a black tea flavor but rather desired a green tea flavor, it would clearly have been obvious to have eliminated the fermenting and firing steps. In any case, Clausi et al. teaches that it has been conventional to perform an extraction (by hot water) using tea leaf that has been treated with supercritical carbon dioxide. Wolnzach also teaches the concept of producing a dried green tea (see step "ii" of the abstract), which is achieved after treating the leaves with supercritical carbon dioxide (i.e. pressures and temperatures above carbon dioxide's critical point of 31.1°C and 72.9 atm). Wang also appears to teach treating green tea leaves with supercritical carbon dioxide and subsequently performing an extraction after this treatment (see page 12 of the translation "High-grade green tea is made with extra care to embodiment (four)"). It is noted that Wang also teaches what appears to be tea leaves, which have been treated with supercritical carbon dioxide, which result in improved flavor (see top of page 12 of the translation). Funahashi et al. is similar to these references in that Funahashi also first employs a hot water extraction with the subsequent decaffeination steps (see

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paragraph 0031 and 0033 of the machine translation). Once the art recognized performing an extraction using tea leaves that have been treated with supercritical carbon dioxide, to therefore modify the combination and employ a conventional green tea leaf from which to further employ activated carbon and clay for further removal of caffeine would thus have been obvious to one having ordinary skill in the art.

11. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 12, 16, 17 and 22, above and in further view of Yumoto et al. (JP10-004919), Tsai (US 4946701) and Niino et al. (US 20030185950).

Claim 19 recites that the low-caffeine green tea extract has a ratio of catechins to caffeine of 25 to 200. The previous combination teaches low caffeine content in the green tea extract but is silent as to the particular ratio. Regarding this limitation, it is noted that Yumoto teaches filtering a green tea extract such that the extract has low amounts of caffeine which still maintaining the desired amount of catechins (see paragraph 0001 of the translation, for instance). Additionally, Yumoto teaches that caffeine has useful physiological functions but also results in an intake of caffeine that can result in negative effects such as appetite loss, and headaches for instance (see paragraph 0004 and 0020 of the translation). In one example, Yumoto teaches that the extract, which after filtration is 69grams, has 39.8% catechins and 0.8% caffeine in the tea extract. This results in a ratio of catechins to caffeine of 49.75. $((69 \times 39.8/100) \text{ divided by } (69 \times 0.8/100))$. Yumoto et al. teaches that this extract can then be used in beverages (see paragraph 0044, for instance). Yumoto even teaches employing

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activated carbon for removing caffeine. Additionally, Tsai also teaches that a ratio of catechins to caffeine of 30 to 1 was desirable. Therefore, to modify the combination and achieve a particular conventional ratio of catechins to caffeine would thus have been obvious to one having ordinary skill in the art, for the purpose of achieving the desired effects of caffeine without the negative physiological effects from caffeine. It is noted that Niino et al. has only been cited as evidence that caffeine can complex with polyphenols (i.e. catechins) that have been oxidized and can thus result in an alteration of the color in the beverage (see paragraph 0006). Therefore, to lower the amount of caffeine would further have been obvious to one having ordinary skill in the art, for the purpose of preventing this change in color due to complexing of polyphenols with caffeine. Additionally, however, to still keep an amount of caffeine in the beverage would have been obvious to the ordinarily skilled artisan in view of the references above, which teach that an amount of caffeine has been desirable for its physiological effects.

12. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 12, 16, 17 and 22, above, and in further view of Nakamura et al. (JP06-142405), for the reasons given in the previous Office Action, mailed November 30, 2009.

13. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references applied to claims 12, 16, 17 and 22, above and in further view of

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Kuraraycoal, as evidenced by Okamoto et al. (US 4026795) and Inagaki et al. (US 5393329).

Regarding claim 26, the combination as applied to claim 12 already teaches the use of activated carbon but is silent as to the claimed pore volume. It is noted however, that applicants employ a commercially available activated carbon, such as KURARAYCOAL GLC. It is noted that Kuraraycoal has been cited as evidence that it has been conventional to use KURARAYCOAL GLC as an adsorbent for removal of materials from a liquid phase. This document as well as Okamoto et al. teach that activated carbon facilitates removal of color and for refining of intermediate and final product (see column 1, lines 15-23 and Example 2 on column 8, lines 35-57).

Regarding the pore volume, since KURARAYCOAL GLC is the same material that applicants have employed, it would thus have had the claimed pore volume. In any case, Inagaki et al. has been relied on as further evidence that KURARAYCOAL activated carbon has a pore volume of 0.65, which thus falls within the claimed range (see table 1). Obviously, the particular pore-volume would thus have been a function of the degree of removal of the undesirable components, as well as based on the size of the components to be removed from the liquid. To therefore employ a particular conventional pore volume to the activated carbon would thus have been an obvious result effective variable, routinely determined through experimentation, especially since the art has recognized employing activated carbon for producing low-caffeine green tea extract.

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14. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 12, 16, 17 and 22, above and in further view of Rong et al. (CN 1421426).

Claim 27 recites that the activated carbon has been added in a proportion of from 0.5 to 3 weight parts to 100 weight parts of said mixture of organic solvent and water.

Regarding this limitation, the above combination appears silent in this regard.

Nevertheless, it is noted that the particular amount of activated carbon employed would indeed have been routinely determined through experimentation for the purpose of achieving optimal removal of the desired components. In any case, Rong et al. teaches employing activated carbon in a ratio to the solvent, such as 95% ethanol, can be 1-10 (see page 6 of the translation). Additionally, in example 1, Rong et al. teaches using 1 gram of activated carbon per 50 ml of the ethanol solvent. Per 100 weight parts, this would result in a ratio of 2 weight parts activated carbon to 100 weight parts of the solvent. Thus, to modify the combination and employ a particular amount of activated carbon compared to the amount of the organic solvent would thus have been obvious to one having ordinary skill in the art, for the purpose of achieving the desired removal of the caffeine, for instance, from the tea extract.

15. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 12, 16, 17 and 22, above and in further view of Hatano et al. (EP1120379).

Regarding claim 28, the combination as applied to claim 12 teaches the use of activated or acid clay, but appears silent as to the particular surface area, as recited in claim 28. It is noted however, that Hatano et al. teaches that activated clay adsorbents (see paragraph 0009), wherein the clay has a surface area within the claimed range (see table 1 on page 13). Hatano et al. further teach that the surface area is also related to the particle size and pore volume (paragraph 0033-034 and 0045).

Nevertheless, Hatano also teaches a pore volume which results in the desired affinity to the material to be adsorbed (see paragraph 0034-0035). Since activated clay having the claimed surface area has been conventionally employed as an adsorbent, to thus modify the combination and employ activated clay having a surface area of $300\text{m}^2/\text{g}$ would thus have been an obvious result effective variable, routinely determined by experimentation, for the purpose of achieving the desired affinity to the material to be adsorbed.

16. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 12, 16, 17 and 22, above and in further view of Nakamura et al. (JP06-142405).

Regarding claim 29, which recites the ratio of activated carbon to activated claim is from 1:1 to 1:6, it is noted that the combination as applied to claim 12 appears silent in this regard. The combination already teaches employing both active carbon and active clay or acid clay. Nevertheless, Nakamura teaches treating 40 mg of tea using 1

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gram of acid clay as well as activated carbon (see paragraph 0005 and example) for the purpose of removing a particular amount of caffeine from the tea extract. Since the combination already teaches using both active carbon and active clay together for removing components of a green tea extract, to thus employ both the activated carbon and acid or activated clay, thus resulting in a ratio of 1:1 would thus have been an obvious result effective variable, routinely determined through experimentation, for the purpose of achieving the optimal adsorption results from both the carbon and the clay.

Response to Arguments

17. The declaration under 37 CFR 1.132 filed April 23, 2010 has been considered but is insufficient to overcome the rejection of the claims as set forth in the last Office action.

The declaration describes an enhancement in caffeine removal and coloration of the green tea extract, by using a combination and activated clay and acid or activated clay and a mixture of 91-97% organic solvent and water.

It is initially noted that the declaration is not commensurate with the independent claim. For instance, although example 1 in the declaration employing a ratio of organic solvent to water of 95:5, it is noted that the claim recites a range that is broader than that shown in the table. Additionally, the claim does not specify a particular amount of activated carbon and acid clay, which is shown in the table. Furthermore, it is noted that the combination clearly teaches that both activated carbon and acid clay have been

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recognized to be used together, for the purpose of adsorbing caffeine. Additionally, it is noted that Klima further evidences this point on column 3, lines 18-23). Therefore, it would not appear to be an unexpected result to achieve additional/improved removal of caffeine by employing two materials, which have been recognized to be used together, for the purpose of removing caffeine from a tea extract.

Regarding the color improvements, it is noted that the art has recognized that caffeine can complex with other components in green tea, which can result in a change in color, as discussed by Niino. Therefore, the art has also recognized that the removal of caffeine also affects the particular color of the green tea. Thus, it would not appear to be unexpected to achieve improved color in green tea by using multiple adsorbents together, for the purpose of removing caffeine, especially since the art has recognized employing applicants' claimed adsorbents together for this purpose.

Additionally, it is noted that the art has also recognized that adsorbents such as activated carbon and activated clay and also aid in removal of undesired color from a liquid.

Regarding the ratio of ethanol to water in the process, it is noted that the art clearly teaches that this ratio has been a conventional ratio employed for the removal of caffeine from a green tea extract. This has been evidenced by Bailey et al. as well as by Rong et al. (CN1421426). Since this ratio has been a conventional ratio used to remove caffeine from green tea, it would still have been obvious to the ordinarily skilled artisan to employ this ratio, since the art recognized that this ratio facilitates removal of caffeine.

18. On page 10 of the response, applicants urge that the machine language translation does not make clear whether the extraction has been conducted in the present of a combination of an organic solvent and water. It is noted however, that the extraction with ethanol solutions is then filtered using filter paper covered with the activated clay (see the examples), thus teaching that the green tea, solvent and adsorbent come into contact with one another. In any case, it is noted that Bailey clearly teaches this concept as well and even further teaches the use of an organic solvent, water combination which is within the claimed range and for the purpose of removing caffeine from the extract.

19. On page 13 of the response, applicants urge that comparative examples 2-4 on the provided table show that a reduction in caffeine was not detected when using either adsorbent alone. It is also further urged that using a mixture of only 70 wt% ethanol in water in combination with activated carbon and clay removed caffeine but also removed catechins from the extract. It is noted however, that claim 12 recites in the preamble, a process for production of a low caffeine green tea extract containing from 25 to 90 wt% non-polymer catechins. In this case, each of the comparative examples still has an amount of non-polymer catechins within the recited range. Inventive example 1 and comparative examples 2-4 have a concentration of non-polymer catechins of 66, 61, 63 and 64% respectively. Comparative example 1 has a non-polymer catechins

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concentration of 49%. However, all these values are still within the range as recited in claim 12.

20. Further on page 13 of the response, applicants assert that Hall fails to provide evidence that Funahashi et al. discloses the use of an acid clay. It is noted however, that Funahashi et al even further teaches activated clay such as magnesium silicate (see paragraph 0033 of the machine translation). Applicants urge that Hall fails to suggest any enhancement in the caffeine removal by using a combination of activated carbon and acid clay. It is noted however, that the combination, as discussed above, already teaches that it has been conventional to use a combination of clay and activated carbon, for the purpose.

21. On page 14 of the response, applicants reiterate the above argument with respect to the Katz reference. It is noted however, that Katz, in claim 8, teaches that combinations of adsorbents for adsorbing caffeine and thus teaches that the art has recognized using activated carbon and clay together for their art recognized and applicants' intended function.

22. Further on page 14 of the response, regarding the Bailey reference, applicants assert that using 95% ethanol for desorption of catechins from an adsorbent fails to suggest using 95% ethanol in the adsorption of caffeine on an adsorbent. This argument is not persuasive. Applicants' arguments are not commensurate in scope

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with the claims, which only recite contact of the green tea with the organic solvent and water mixture and an adsorbent. In any case, it is noted that by desorbing the catechins from the adsorption material which also now has the caffeine adsorbed thereon, the reference still teaches separating caffeine from green tea extract.

23. On page 14-15 of the response, applicants assert that while dissolution of dry green tea extract may be conventional in the isolation of flavanols by liquid extraction, such does not suggest dissolving green tea extract in an organic solvent and water for treatment with a solid adsorbent.

It is noted however, that the combination as applied to claim 12 already teaches this limitation. Tsai was only relied on as evidence that it has been conventional to dissolve a green tea extract in an organic solvent and for facilitating additional extraction steps.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 4411923 discloses treating a tea mixture with supercritical carbon dioxide, resulting in a dried tea product (see example 3).

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JP02-41165 discloses a treated residue obtained from treatment of tea leaves with supercritical fluids, which results in removal of caffeine while still retaining tannin components.

JP71-039058 discloses using activated charcoal to an extraction of tea leaves in an organic solvent to remove the impurities in the tea leaves.

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VIREN THAKUR whose telephone number is (571)272-6694. The examiner can normally be reached on Monday through Friday from 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571)-272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1782

/Rena L. Dye/
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